In the second paragraph the first sentence is new and eliminates difficulties arising from unrecorded interests.

The second sentence is based on Title 35, U.S.C., 1946 ed., § 72a (Mar. 3, 1927, ch. 364, 44 Stat. 1394, reenacted Oct. 31, 1951, ch. 655, § 53a, 65 Stat. 728) with changes in language.

The fourth sentence is new and prevents such suits from being filed against the Commissioner as a defendant; however, the Commissioner has the right to intervene.

Language is changed.

AMENDMENTS

1984—Pub. L. 98–622 substituted ''Board of Patent Appeals and Interferences on the interference'' for ''board of patent interference on the question of priority''.

1982—Pub. L. 97–164 substituted ''Court of Appeals for the Federal Circuit'' for ''Court of Customs and Patent Appeals''.

1975—Pub. L. 93–596 substituted ''Patent and Trademark Office'' for ''Patent Office'' wherever appearing.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–622 effective three months after Nov. 8, 1984, see section 207 of Pub. L. 98–622, set out as a note under section 7 of this title.

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97–164 effective Oct. 1, 1982, see section 402 of Pub. L. 97–164, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 93–596 effective Jan. 2, 1975, see section 4 of Pub. L. 93–596, set out as a note under section 1111 of Title 15, Commerce and Trade.

CROSS REFERENCES

Section applicable to action for adjudication of validity of interfering patents, see section 291 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 141, 291 of this title; title 28 section 1295.

CHAPTER 14—ISSUE OF PATENT

AMENDMENTS

1984—Pub. L. 98–622, title I, § 102(b), Nov. 8, 1984, 98 Stat. 3384, added item 157.

Pub. L. 98–417, title II, § 201(b), Sept. 24, 1984, 98 Stat. 1602, added item 156.

1983—Pub. L. 98–127, § 4(b), Oct. 13, 1983, 97 Stat. 833, added item 155A.

Pub. L. 97–414, § 11(b), Jan. 4, 1983, 96 Stat. 2066, added item 155.

1965—Pub. L. 89–83, § 6, July 24, 1965, 79 Stat. 261, substituted ''Issue of patent'' for ''Time of issue of patent'' in item 151.

§ 151. Issue of patent

If it appears that applicant is entitled to a patent under the law, a written notice of allowance of the application shall be given or mailed to the applicant. The notice shall specify a sum, constituting the issue fee or a portion thereof, which shall be paid within three months thereafter.

Upon payment of this sum the patent shall issue, but if payment is not timely made, the application shall be regarded as abandoned.

Any remaining balance of the issue fee shall be paid within three months from the sending of a notice thereof and, if not paid, the patent shall lapse at the termination of this three-month period. In calculating the amount of a remaining balance, charges for a page or less may be disregarded.

If any payment required by this section is not timely made, but is submitted with the fee for delayed payment and the delay in payment is shown to have been unavoidable, it may be accepted by the Commissioner as though no abandonment or lapse had ever occurred.

(July 19, 1952, ch. 950, 66 Stat. 803; Pub. L. 89–83, § 4, July 24, 1965, 79 Stat. 260; Pub. L. 93–601, § 3, Jan. 2, 1975, 88 Stat. 1956.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 41 (R.S. 4885, amended (1) May 23, 1908, ch. 189, 35 Stat. 246, (2) Aug. 9, 1939, § 2, ch. 619, 53 Stat. 1293).

Language is changed.

AMENDMENTS

1975—Pub. L. 93–601 substituted ''and the delay in payment is shown to have been unavoidable,'' for ''within three months after the due date and sufficient cause is shown for the late payment,'' in last par.

1965—Pub. L. 89–83 substituted provisions requiring a notice of allowance to be sent to the applicant, the notice of allowance to specify a sum, constituting the issue fee or a portion thereof, which shall be paid within 3 months thereafter, the patent to issue upon payment of this sum, the application to be deemed abandoned if the sum is not paid, and any remaining balance of the fee to be paid within 3 months after issuance of the patent shall lapse, and permitting the Commissioner within 3 months after the due date of an unpaid fee on a showing of sufficient cause to accept late payment as though no abandonment or lapse had occurred, for provisions which required a notice of allowance to be sent to the applicant, the final fee to be paid within 6 months after the notice, the patent to be issued within 3 months from the date of the payment, and which permitted delayed payment of the issue fee up to 1 year.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 93–601 effective Jan. 2, 1975, with examiners-in-chief in office on such date to continue with existing appointment, see section 4(b) of Pub. L. 93–601, set out as a note under section 3 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–83 effective three months after July 24, 1965, see section 7(a) of Pub. L. 89–83, set out as a note under section 41 of this title.

ACCEPTANCE OF LATE PAYMENT OF ISSUE FEES BY COMMISSIONER

Section 4(a) of Pub. L. 93–601 provided that: ''The Commissioner of Patents [now Patents and Trademarks] may, in accordance with Section 3 of this Act [amending this section], accept late payment of issue fees, the payment of which was governed by the provisions of Public Law 89–93 [probably should refer to Public Law 89–83, which amended sections 41, 112, and 151 of this title and section 1113 of Title 15, Commerce and

Trade]; *Provided*: the term of the patent for which late payment of such an issue fee is accepted shall expire earlier than the time specified in Section 154 of Title 35, United States Code by a period equal to the delay between the time the application became abandoned or the patent lapsed for failure to pay the issue fee and the time the late payment is accepted after enactment of this Act [Jan. 2, 1975]; *Further Provided*: no patent with respect to which the issue fee was governed by the provisions of PL 89–83 and for which a late payment of the issue fee is accepted under the authority created by Section 3 of this Act, shall abridge or affect the right of any person or his successors in business who made, purchased or used anything covered by the patent, after the date of the application became abandoned or patent lapsed for failure to pay the issue fee but prior to the grant or restoration of the patent, to continue the use of or to sell to others to be used or sold, the specific thing so made, purchased, or used. A court before which such matter is in question may provide for the continued manufacture, use or sale of the thing made, purchased or used as specified, or for the manufacture, use or sale of which substantial preparation was made after the date the application became abandoned or patent lapsed for failure to pay the fee but prior to the grant or restoration of the patent, and it may also provide for the continued practice of any process covered by the patent, practiced, or for the practice of which substantial preparation was made, after the date the application became abandoned or patent lapsed for failure to pay the issue fee but prior to the grant or restoration of the patent, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced before the grant or restoration of the patent.''

CROSS REFERENCES

Patent fees, see section 41 of this title.
Payment of fees, see section 42 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 41, 267 of this title.

§ 152. Issue of patent to assignee

Patents may be granted to the assignee of the inventor of record in the Patent and Trademark Office, upon the application made and the specification sworn to by the inventor, except as otherwise provided in this title.

(July 19, 1952, ch. 950, 66 Stat. 804; Pub. L. 93–596, §1, Jan. 2, 1975, 88 Stat. 1949.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §44 (R.S. 4895).
Language is changed and the reference to reissue is omitted in view of the general provision in section 251.

AMENDMENTS

1975—Pub. L. 93–596 substituted ''Patent and Trademark Office'' for ''Patent Office''.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 93–596 effective Jan. 2, 1975, see section 4 of Pub. L. 93–596, set out as a note under section 1111 of Title 15, Commerce and Trade.

CROSS REFERENCES

Application for patent by assignee, see section 118 of this title.
Ownership of patent, assignment of, see section 261 of this title.
Reissue of patent by assignee, see section 261 of this title.

§ 153. How issued

Patents shall be issued in the name of the United States of America, under the seal of the Patent and Trademark Office, and shall be signed by the Commissioner or have his signature placed thereon and attested by an officer of the Patent and Trademark Office designated by the Commissioner, and shall be recorded in the Patent and Trademark Office.

(July 19, 1952, ch. 950, 66 Stat. 804; Pub. L. 93–596, §1, Jan. 2, 1975, 88 Stat. 1949.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §39 (R.S. 4883, amended (1) Feb. 18, 1888, ch. 15, 25 Stat. 40, (2) April 11, 1903, ch. 417, 32 Stat. 95, (3) Feb. 18, 1922, ch. 58, §5, 42 Stat. 391).
The phrases referring to the attesting officers and to the recording of the patents are broadened.

AMENDMENTS

1975—Pub. L. 93–596 substituted ''Patent and Trademark Office'' for ''Patent Office'' wherever appearing.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 93–596 effective Jan. 2, 1975, see section 4 of Pub. L. 93–596, set out as a note under section 1111 of Title 15, Commerce and Trade.

CROSS REFERENCES

Seal, see section 2 of this title.

§ 154. Contents and term of patent

(a) IN GENERAL.—

(1) CONTENTS.—Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

(2) TERM.—Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

(3) PRIORITY.—Priority under section 119, 365(a), or 365(b) of this title shall not be taken into account in determining the term of a patent.

(4) SPECIFICATION AND DRAWING.—A copy of the specification and drawing shall be annexed to the patent and be a part of such patent.

(b) TERM EXTENSION.—

(1) INTERFERENCE DELAY OR SECRECY ORDERS.—If the issue of an original patent is delayed due to a proceeding under section 135(a) of this title, or because the application for patent is placed under an order pursuant to section 181 of this title, the term of the patent shall be extended for the period of delay, but in no case more than 5 years.

(2) EXTENSION FOR APPELLATE REVIEW.—If the issue of a patent is delayed due to appellate

review by the Board of Patent Appeals and Interferences or by a Federal court and the patent is issued pursuant to a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended for a period of time but in no case more than 5 years. A patent shall not be eligible for extension under this paragraph if it is subject to a terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review.

(3) LIMITATIONS.—The period of extension referred to in paragraph (2)—

(A) shall include any period beginning on the date on which an appeal is filed under section 134 or 141 of this title, or on which an action is commenced under section 145 of this title, and ending on the date of a final decision in favor of the applicant;

(B) shall be reduced by any time attributable to appellate review before the expiration of 3 years from the filing date of the application for patent; and

(C) shall be reduced for the period of time during which the applicant for patent did not act with due diligence, as determined by the Commissioner.

(4) LENGTH OF EXTENSION.—The total duration of all extensions of a patent under this subsection shall not exceed 5 years.

(c) CONTINUATION.—

(1) DETERMINATION.—The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

(2) REMEDIES.—The remedies of sections 283, 284, and 285 of this title shall not apply to acts which—

(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

(3) REMUNERATION.—The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.

(July 19, 1952, ch. 950, 66 Stat. 804; Pub. L. 89–83, § 5, July 24, 1965, 79 Stat. 261; Pub. L. 96–517, § 4, Dec. 12, 1980, 94 Stat. 3018; Pub. L. 100–418, title IX, § 9002, Aug. 23, 1988, 102 Stat. 1563; Pub. L. 103–465, title V, § 532(a)(1), Dec. 8, 1994, 108 Stat. 4983; Pub. L. 104–295, § 20(e)(1), Oct. 11, 1996, 110 Stat. 3529.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 40 (R.S. 4884, amended May 23, 1930, ch. 312, § 1, 46 Stat. 376).

The reference to plants is omitted for inclusion in another section and the reference to the title is shortened since the title is of no legal significance.

The wording of the granting clause is changed to ''the right to exclude others from making, using, or selling'', following language used by the Supreme Court, to render the meaning clearer.

''United States'' is defined in section 100.

REFERENCES IN TEXT

The date of the enactment of the Uruguay Round Agreements Act, referred to in subsec. (c)(1), (2)(A), is the date of enactment of Pub. L. 103–465, which was approved Dec. 8, 1994.

AMENDMENTS

1996—Subsec. (c)(2). Pub. L. 104–295 substituted ''acts'' for ''Acts'' in introductory provisions.

1994—Pub. L. 103–465 amended section catchline and text generally. Prior to amendment, text read as follows: ''Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, subject to the payment of fees as provided for in this title, of the right to exclude others from making, using, or selling the invention throughout the United States and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process,, referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof.''

1988—Pub. L. 100–418 inserted ''and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process,'' after ''United States''.

1980—Pub. L. 96–517 substituted ''payment of fees'' for ''payment of issue fees''.

1965—Pub. L. 89–83 added ''subject to the payment of issue fees as provided for in this title''.

EFFECTIVE DATE OF 1994 AMENDMENT

Section 534 of title V of Pub. L. 103–465 provided that: ''(a) IN GENERAL.—Subject to subsection (b), the amendments made by this subtitle [subtitle C (§§ 531–534) of title V of Pub. L. 103–465, amending this section and sections 41, 104, 111, 119, 156, 172, 173, 252, 262, 271, 272, 287, 292, 295, 307, 365, and 373 of this title] take effect on the date that is one year after the date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995].

''(b) PATENT APPLICATIONS.—

''(1) IN GENERAL.—Subject to paragraph (2), the amendments made by section 532 [amending this section and sections 41, 111, 119, 156, 172, 173, 365, and 373 of this title] take effect on the date that is 6 months after the date of the enactment of this Act [Dec. 8, 1994] and shall apply to all patent applications filed in the United States on or after the effective date.

''(2) SECTION 154(a)(1).—Section 154(a)(1) of title 35, United States Code, as amended by section 532(a)(1) of this Act, shall take effect on the effective date described in subsection (a).

''(3) EARLIEST FILING.—The term of a patent granted on an application that is filed on or after the effective date described in subsection (a) and that contains a specific reference to an earlier application filed under the provisions of section 120, 121, or 365(c) of title 35, United States Code, shall be measured from the filing date of the earliest filed application.''

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–418 effective 6 months after Aug. 23, 1988, and, subject to enumerated exceptions, applicable only with respect to products made or imported after such effective date, see section 9006 of Pub. L. 100–418, set out as a note under section 271 of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by Pub. L. 96–517 effective Dec. 12, 1980, see section 8(a) of Pub. L. 96–517, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–83 effective three months after July 24, 1965, see section 7(a) of Pub. L. 89–83, set out as a note under section 41 of this title.

REGULATIONS

Section 532(a)(2) of Pub. L. 103–465 provided that:

''(A) The Commissioner of Patents and Trademarks shall prescribe regulations to provide for further limited reexamination of applications that have been pending for 2 years or longer as of the effective date of section 154(a)(2) of title 35, United States Code [see Effective Date of 1994 Amendment note above], as added by paragraph (1) of this subsection, taking into account any reference made in such application to any earlier filed application under section 120, 121, or 365(c) of such title. The Commissioner may establish appropriate fees for such further limited reexamination.

''(B) The Commissioner of Patents and Trademarks shall prescribe regulations to provide for the examination of more than 1 independent and distinct invention in an application that has been pending for 3 years or longer as of the effective date of section 154(a)(2) of title 35, United States Code, as added by paragraph (1) of this subsection, taking into account any reference made in such application to any earlier filed application under section 120, 121, or 365(c) of such title. The Commissioner may establish appropriate fees for such examination.''

CROSS REFERENCES

Design patent, term of, see section 173 of this title.
Plant patents, grant of, see section 163 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 103, 155, 155A of this title.

§ 155. Patent term extension

Notwithstanding the provisions of section 154, the term of a patent which encompasses within its scope a composition of matter or a process for using such composition shall be extended if such composition or process has been subjected to a regulatory review by the Federal Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act leading to the publication of regulation permitting the interstate distribution and sale of such composition or process and for which there has thereafter been a stay of regulation of approval imposed pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act which stay was in effect on January 1, 1981, by a length of time to be measured from the date such stay of regulation of approval was imposed until such proceedings are finally resolved and commercial marketing permitted. The patentee, his heirs, successors or assigns shall notify the Commissioner of Patents and Trademarks within ninety days of the date of enactment of this section or the date the stay of regulation of approval has been removed, whichever is later, of the number of the patent to be extended and the date the stay was imposed and the date commercial marketing was permitted. On receipt of such notice, the Commissioner shall promptly issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the composition of matter or process for using such composition to which such extension is applicable. Such certificate shall be recorded in the official file of each patent extended and such certificate shall be considered as part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office.

(Added Pub. L. 97–414, §11(a), Jan. 4, 1983, 96 Stat. 2065.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. Section 409 of the Federal Food, Drug, and Cosmetic Act is classified to section 348 of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Date of enactment of this section, referred to in text, means date of enactment of Pub. L. 97–414, which was approved Jan. 4, 1983.

§ 155A. Patent term restoration

(a) Notwithstanding section 154 of this title, the term of each of the following patents shall be extended in accordance with this section:

(1) Any patent which encompasses within its scope a composition of matter which is a new drug product, if during the regulatory review of the product by the Federal Food and Drug Administration—

(A) the Federal Food and Drug Administration notified the patentee, by letter dated February 20, 1976, that such product's new drug application was not approvable under section 505(b)(1) of the Federal Food, Drug and Cosmetic Act;

(B) in 1977 the patentee submitted to the Federal Food and Drug Administration the results of a health effects test to evaluate the carcinogenic potential of such product;

(C) the Federal Food and Drug Administration approved, by letter dated December 18, 1979, the new drug application for such product; and

(D) the Federal Food and Drug Administration approved, by letter dated May 26, 1981, a supplementary application covering the facility for the production of such product.

(2) Any patent which encompasses within its scope a process for using the composition of matter described in paragraph (1).

(b) The term of any patent described in subsection (a) shall be extended for a period equal to the period beginning February 20, 1976, and ending May 26, 1981, and such patent shall have the effect as if originally issued with such extended term.

(c) The patentee of any patent described in subsection (a) of this section shall, within ninety days after the date of enactment of this section, notify the Commissioner of Patents and Trademarks of the number of any patent so extended. On receipt of such notice, the Commissioner shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension in the Official Gazette of the Patent and Trademark Office.

(Added Pub. L. 98–127, §4(a), Oct. 13, 1983, 97 Stat. 832.)

REFERENCES IN TEXT

Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act, referred to in subsec. (a)(1)(A), is classified to section 355(b)(1) of Title 21, Food and Drugs.

The date of enactment of this section, referred to in subsec. (c), is the date of enactment of Pub. L. 98–127, which was approved Oct. 13, 1983.

§ 156. Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which—

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the ''approved product''.

(b) Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended—

(1) in the case of a patent which claims a product, be limited to any use approved for the product—

(A) before the expiration of the term of the patent—

(i) under the provision of law under which the applicable regulatory review occurred, or

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product—

(A) before the expiration of the term of the patent—

(i) under any provision of law under which an applicable regulatory review occurred, and

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; and

(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make—

(A) the approved product, or

(B) the product if it has been subject to a regulatory review period described in paragraphs[1] (1), (4), or (5) of subsection (g).

As used in this subsection, the term ''product'' includes an approved product.

(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and

(4) in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

[1] So in original. Probably should be ''paragraph''.

(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Commissioner. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain—

(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

(C) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

(E) such patent or other information as the Commissioner may require.

(2)(A) Within 60 days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify—

(i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus-Serum-Toxin Act, and

(ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,

of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than 30 days after the receipt of an application from the Commissioner, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

(B)(i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than 180 days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by such Secretary, determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary making the determination shall make such determination not later than 90 days after the receipt of such a petition. For a drug product, device, or additive subject to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, the Secretary may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Commissioner of Food and Drugs. For a product subject to the Virus-Serum-Toxin Act, the Secretary of Agriculture may not delegate the authority to make the determination prescribed by this clause to an office below the office[2] of the Assistant Secretary for Marketing and Inspection Services.

(ii) The Secretary making a determination under clause (i) shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than 30 days after the date of the request, or at the request of the person making the request, not later than 60 days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and shall notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.

(3) For the purposes of paragraph (2)(B), the term ''due diligence'' means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Commissioner.

(5)(A) If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Commissioner for an interim extension during the period beginning 6 months, and ending 15 days, before such term is due to expire. The application shall contain—

(i) the identity of the product subject to regulatory review and the Federal statute under which such review is occurring;

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[2] So in original. Probably should be capitalized.

(ii) the identity of the patent for which interim extension is being sought and the identity of each claim of such patent which claims the product under regulatory review or a method of using or manufacturing the product;

(iii) information to enable the Commissioner to determine under subsection (a)(1), (2), and (3) the eligibility of a patent for extension;

(iv) a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date with respect to the product under review and the significant dates applicable to such activities; and

(v) such patent or other information as the Commissioner may require.

(B) If the Commissioner determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Commissioner shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year.

(C) The owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

(D) Each certificate of interim extension under this paragraph shall be recorded in the official file of the patent and shall be considered part of the original patent.

(E) Any interim extension granted under this paragraph shall terminate at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use, except that, if within that 60-day period the applicant notifies the Commissioner of such permission and submits any additional information under paragraph (1) of this subsection not previously contained in the application for interim extension, the patent shall be further extended, in accordance with the provisions of this section—

(i) for not to exceed 5 years from the date of expiration of the original patent term; or

(ii) if the patent is subject to subsection (g)(6)(C), from the date on which the product involved receives approval for commercial marketing or use.

(F) The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension—

(i) in the case of a patent which claims a product, be limited to any use then under regulatory review;

(ii) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and

(iii) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

(e)(1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

(2) If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

(f) For purposes of this section:

(1) The term ''product'' means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term ''drug product'' means the active ingredient of—

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or

(B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques,

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(3) The term ''major health or environmental effects test'' means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

(B) Any reference to section 503, 505, 512, or 515 is a reference to section 503, 505, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151–158).

(5) The term ''informal hearing'' has the meaning prescribed for such term by section 201(y)[3] of the Federal Food, Drug, and Cosmetic Act.

(6) The term ''patent'' means a patent issued by the United States Patent and Trademark Office.

(7) The term ''date of enactment'' as used in this section means September 24, 1984, for a human drug product, a medical device, food additive, or color additive.

(8) The term ''date of enactment'' as used in this section means the date of enactment of the Generic Animal Drug and Patent Term Restoration Act for an animal drug or a veterinary biological product.

(g) For purposes of this section, the term ''regulatory review period'' has the following meanings:

(1)(A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of—

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507[3] became effective for the approved product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507,[3] and

(ii) the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507[3] and ending on the date such application was approved under such section.

(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a food or color additive is the sum of—

(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a medical device is the sum of—

(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(4)(A) In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new animal drug product is the sum of—

(i) the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512, and

(ii) the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

(5)(A) In the case of a product which is a veterinary biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory period for a veterinary biological product is the sum of—

(i) the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act, and

(ii) the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(6) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of the enactment of this section,

[3] See References in Text note below.

the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B) If the patent involved was issued before the date of the enactment of this section and—

(i) no request for an exemption described in paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted,

(ii) no major health or environmental effects test described in paragraph (2)(B) or (4)(B) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

(iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submittted,[4]

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years.

(h) The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.

(Added Pub. L. 98–417, title II, § 201(a), Sept. 24, 1984, 98 Stat. 1598; amended Pub. L. 100–670, title II, § 201(a)–(h), Nov. 16, 1988, 102 Stat. 3984–3987; Pub. L. 103–179, §§ 5, 6, Dec. 3, 1993, 107 Stat. 2040, 2042; Pub. L. 103–465, title V, § 532(c)(1), Dec. 8, 1994, 108 Stat. 4987; Pub. L. 105–115, title I, § 125(b)(2)(P), Nov. 21, 1997, 111 Stat. 2326.)

REFERENCES IN TEXT

The Virus-Serum-Toxin Act, referred to in subsecs. (d)(2)(A)(i), (B)(i), (f)(2)(B), (4)(C), and (g)(5)(B), (6)(C), is act Mar. 4, 1913, ch. 145, 37 Stat. 828, as amended, which is classified generally to chapter 5 (§ 151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (d)(2)(A)(ii), (B)(ii), (f), and (g)(2)(B), (3)(B)(ii), (6)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

[4] So in original. Probably should be ''submitted,''.

The Public Health Service Act, referred to in subsecs. (d)(2)(B)(i) and (f)(2)(A), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Sections 503, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (f)(4)(B) and (g)(1)(B), (3)(B), are classified, respectively, to sections 353, 355, 360b, and 360e of Title 21, Food and Drugs. Section 507 of the Act, referred to in subsec. (g)(1)(B), was classified to section 357 of Title 21, prior to repeal by Pub. L. 105–115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325.

Section 201 of the Federal Food, Drug, and Cosmetic Act, referred to in subsec. (f)(5), which is classified to section 321 of Title 21, was subsequently amended, and section 201(y) no longer defines the term ''informal hearing''. However, such term is defined elsewhere in that section.

Section 351 of the Public Health Service Act, referred to in subsecs. (f)(4)(A) and (g)(1)(B)(i), (ii), is classified to section 262 of Title 42, The Public Health and Welfare.

The date of enactment of the Generic Animal Drug and Patent Term Restoration Act, referred to in subsec. (f)(8), is the date of enactment of Pub. L. 100–670, which was approved Nov. 16, 1988.

The date of the enactment of this section, referred to in subsec. (g)(6), is the date of the enactment of Pub. L. 98–417, which was approved Sept. 24, 1984.

AMENDMENTS

1997—Subsec. (f)(4)(B). Pub. L. 105–115, § 125(b)(2)(P), struck out ''507,'' after ''505,'' in two places.

1994—Subsec. (a)(2). Pub. L. 103–465 inserted ''under subsection (e)(1) of this section'' after ''extended''.

1993—Subsec. (a)(1). Pub. L. 103–179, § 6(1)(A), substituted ''subsection (d)(1)'' for ''subsection (d)''.

Subsec. (a)(3). Pub. L. 103–179, § 6(1)(B), substituted ''paragraphs (1) through (4) of subsection (d)'' for ''subsection (d)''.

Subsec. (b). Pub. L. 103–179, § 6(2), substituted ''Except as provided in subsection (d)(5)(F), the rights'' for ''The rights'' in introductory provisions.

Subsec. (c)(4). Pub. L. 103–179, § 5(1), substituted ''extended under subsection (e)(1)'' for ''extended''.

Subsec. (d)(1). Pub. L. 103–179, § 5(2), substituted ''Except as provided in paragraph (5), such'' for ''Such'' in second sentence.

Subsec. (d)(5). Pub. L. 103–179, § 5(3), added par. (5).

Subsec. (e)(1). Pub. L. 103–179, § 6(3)(A), substituted ''paragraphs (1) through (4) of subsection (d)'' for ''subsection (d)''.

Subsec. (e)(2). Pub. L. 103–179, § 6(3)(B), substituted ''subsection (d)(1)'' for ''subsection (d)''.

1988—Subsec. (a)(5)(A). Pub. L. 100–670, § 201(a)(1), inserted ''or (C)'' after ''in subparagraph (B)''.

Subsec. (a)(5)(C). Pub. L. 100–670, § 201(a)(2), (3), added subpar. (C).

Subsec. (b). Pub. L. 100–670, § 201(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: ''The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

''(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

''(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

''(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.''

Subsec. (c)(2). Pub. L. 100–670, §201(c), substituted ''(3)(B)(i), (4)(B)(i), and (5)(B)(i)'' for ''and (3)(B)(i)''.

Subsec. (d)(1)(C). Pub. L. 100–670, §201(d), inserted ''or the Secretary of Agriculture'' after ''and Human Services''.

Subsec. (d)(2)(A). Pub. L. 100–670, §201(e), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act, of the extension application and shall submit to the Secretary a copy of the application. Not later than thirty days after the receipt of an application from the Commissioner, the Secretary shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.''

Subsec. (d)(2)(B). Pub. L. 100–670, §201(f), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows:

''(i) If a petition is submitted to the Secretary under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary shall, in accordance with regulations promulgated by the Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than ninety days after the receipt of such a petition. The Secretary may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

''(ii) The Secretary shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the sixty-day period beginning on the publication of a determination, the Secretary to hold an informal hearing on the determination. If such a request is made within such period, the Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, the Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.''

Subsec. (f)(1)(A). Pub. L. 100–670, §201(g)(1), struck out ''human'' before ''drug product''.

Subsec. (f)(2). Pub. L. 100–670, §201(g)(1), amended par. (2) generally. Prior to amendment, par. (2) read as follows: ''The term 'human drug product' means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.''

Subsec. (f)(4)(B), (C). Pub. L. 100–670, §201(g)(2), which directed general amendment of subpars. (B) and (C) of par. (4), was executed by amending subpar. (B) generally, and adding subpar. (C) as probable intent of Congress in light of absence of subpar. (C) in par. (4). Prior to amendment, subpar. (B) read as follows: ''Any reference to section 503, 505, 507, or 515 is a reference to section 503, 505, 507, or 515 of the Federal Food, Drug, and Cosmetic Act.''

Subsec. (f)(7), (8). Pub. L. 100–670, §201(g)(3), added pars. (7) and (8).

Subsec. (g)(1)(A). Pub. L. 100–670, §201(h)(1)(A), (2), substituted ''new drug, antibiotic drug, or human biological product'' for ''human drug product'' and ''paragraph (6)'' for ''paragraph (4)''.

Subsec. (g)(1)(B). Pub. L. 100–670, §201(h)(1)(B), substituted ''new drug, antibiotic drug, or human biological product'' for ''human drug product'' in introductory provisions and ''product'' for ''human drug product'' in cls. (i) and (ii).

Subsec. (g)(2)(A), (3)(A). Pub. L. 100–670, §201(h)(3), substituted ''paragraph (6)'' for ''paragraph (4)''.

Subsec. (g)(4), (5). Pub. L. 100–670, §201(h)(4), added pars. (4) and (5). Former par. (4) redesignated (6).

Subsec. (g)(6). Pub. L. 100–670, §201(h)(4), redesignated former par. (4) as (6).

Subsec. (g)(6)(B)(i). Pub. L. 100–670, §201(h)(5)(A), substituted ''paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted'' for ''paragraph (1)(B) was submitted''.

Subsec. (g)(6)(B)(ii). Pub. L. 100–670, §201(h)(5)(B), substituted ''paragraph (2)(B) or (4)(B)'' for ''paragraph (2)''.

Subsec. (g)(6)(C). Pub. L. 100–670, §201(h)(5)(C), inserted ''or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years'' after ''exceed two years''.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective 6 months after Dec. 8, 1994, and applicable to all patent applications filed in the United States on or after that effective date, with provisions relating to earliest filed patent application, see section 534(b)(1), (3) of Pub. L. 103–465, set out as a note under section 154 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 282 of this title.

§ 157. Statutory invention registration

(a) Notwithstanding any other provision of this title, the Commissioner is authorized to publish a statutory invention registration containing the specification and drawings of a regularly filed application for a patent without examination if the applicant—

(1) meets the requirements of section 112 of this title;

(2) has complied with the requirements for printing, as set forth in regulations of the Commissioner;

(3) waives the right to receive a patent on the invention within such period as may be prescribed by the Commissioner; and

(4) pays application, publication, and other processing fees established by the Commissioner.

If an interference is declared with respect to such an application, a statutory invention registration may not be published unless the issue of priority of invention is finally determined in favor of the applicant.

(b) The waiver under subsection (a)(3) of this section by an applicant shall take effect upon publication of the statutory invention registration.

(c) A statutory invention registration published pursuant to this section shall have all of

the attributes specified for patents in this title except those specified in section 183 and sections 271 through 289 of this title. A statutory invention registration shall not have any of the attributes specified for patents in any other provision of law other than this title. A statutory invention registration published pursuant to this section shall give appropriate notice to the public, pursuant to regulations which the Commissioner shall issue, of the preceding provisions of this subsection. The invention with respect to which a statutory invention certificate is published is not a patented invention for purposes of section 292 of this title.

(d) The Secretary of Commerce shall report to the Congress annually on the use of statutory invention registrations. Such report shall include an assessment of the degree to which agencies of the Federal Government are making use of the statutory invention registration system, the degree to which it aids the management of federally developed technology, and an assessment of the cost savings to the Federal Government of the use of such procedures.

(Added Pub. L. 98–622, title I, §102(a), Nov. 8, 1984, 98 Stat. 3383.)

EFFECTIVE DATE

Section 102(c) of Pub. L. 98–622 provided that: ''The amendments made by this section [enacting this section and item 157 in the table of sections of this chapter] shall take effect six months after the date of enactment of this Act [Nov. 8, 1984].''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 111 of this title.

CHAPTER 15—PLANT PATENTS

§ 161. Patents for plants

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.

The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

(June 19, 1952, ch. 950, 66 Stat. 804; Sept. 3, 1954, ch. 1259, 68 Stat. 1190.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §31, part (R.S. 4886, amended (1) Mar. 3, 1897, ch. 391, §1, 29 Stat. 692, (2) May 23, 1930, ch. 312, §1, 46 Stat. 376, (3) Aug. 5, 1939, ch. 450, §1, 53 Stat. 1212).

The provision relating to plants in the corresponding section of existing statute is made a separate section.

AMENDMENTS

1954—Act Sept. 3, 1954, provided that plant seedlings, discovered, propagated asexually, and proved to have new characteristics distinct from other known plants are patentable.

CROSS REFERENCES

Patentability of inventions generally, see section 100 et seq. of this title.

Plant Variety Protection, see section 2321 et seq. of Title 7, Agriculture.

§ 162. Description, claim

No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible.

The claim in the specification shall be in formal terms to the plant shown and described.

(July 19, 1952, ch. 950, 66 Stat. 804.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §33, part (R.S. 4888, amended (1) Mar. 3, 1915, ch. 94, §1, 38 Stat. 958, (2) May 23, 1930, ch. 312, §2, 46 Stat. 376).

The first paragraph is the provision in R.S. 4888 (see section 112). The second paragraph is not in the statute but represents the actual practice.

§ 163. Grant

In the case of a plant patent, the grant shall include the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States.

(July 19, 1952, ch. 950, 66 Stat. 804; Pub. L. 105–289, §3(a), Oct. 27, 1998, 112 Stat. 2781.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §40, part (R.S. 4884, amended May 23, 1930, ch. 312, §1, 46 Stat. 376).

This provision is from R.S. 4884 (see section 154) amended in language.

AMENDMENTS

1998—Pub. L. 105–289 reenacted section catchline without change and amended text generally. Prior to amendment, text read as follows: ''In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced.''

EFFECTIVE DATE OF 1998 AMENDMENT

Pub. L. 105–289, §3(b), Oct. 27, 1998, 112 Stat. 2781, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to any plant patent issued on or after the date of the enactment of this Act [Oct. 27, 1998].''

FINDINGS AND PURPOSES

Pub. L. 105–289, §2, Oct. 27, 1998, 112 Stat. 2780, provided that:

''(a) FINDINGS.—The Congress makes the following findings:

''(1) The protection provided by plant patents under title 35, United States Code, dating back to 1930, has historically benefited American agriculture and horticulture and the public by providing an incentive for breeders to develop new plant varieties.

''(2) Domestic and foreign agricultural trade is rapidly expanding and is very different from the trade of the past. An unforeseen ambiguity in the provisions of title 35, United States Code, is undermining the orderly collection of royalties due breeders holding United States plant patents.

''(3) Plant parts produced from plants protected by United States plant patents are being taken from il-